

REMARKS

Claims 11-12 and 22-33 are pending in the present application. Claims 11-14, 22-24 and 27 were objected to for containing non-elected subject matter. Claims 11-14, 22-24 and 27 were rejected under 35 U.S.C. § 112, first paragraph.

Claims 11, 12, 22 and 23 have been amended. Support for the amendments can be found throughout the specification, for example:

- support for the reaction mixture having a pH between 6.5 and 8.0 is located, for example, in paragraphs [0020] and [0042];
- support for the use of tetrahydrofuran in the reaction mixture is set forth, for example, in paragraph [0020] and in the sentence immediately preceding paragraph [0042]; and
- support for the addition of cyclic hydrocarbon solvent selected from the group consisting of cyclohexane and methyl cyclohexane is set forth, for example, in paragraphs [0021] and [0043].

Reference is also made to the various examples such as, for example, Example 5, in paragraphs [0067] to [0073]. All of the aforementioned paragraph references are to the published US application, US 2006/0287538 A1. No new matter has been added.

Reconsideration of the application is respectfully requested.

Claim Objection

Claims 11-14, 22-24 and 27 were objected to for containing non-elected subject matter.

In their response to the Restriction Requirement dated August 27, 2008, Applicants provisionally elected with traverse to initially prosecute the species of Example 5 where the cyclic hydrocarbon solvent can be methylcyclohexane or cyclohexane. Applicants have amended the claims of the present application to reflect said species. The present amendments include:

- incorporation of "tetrahydrofuran" as a "nonhydroxylic organic solvent" in claims 11 and 12. Cancelling of claim 13;

- deletion of references to the non-cyclic chlorinated organic solvents in claims 11, 22 and 23; and
- deletion of references to the cyclic hydrocarbon solvent cyclopentane in claims 11.

Applicants respectfully submit that the claims of the present application as amended do not now contain non-elected subject matter.

Reconsideration of the application is respectfully requested.

Rejections under 35 U.S.C. § 112

Claims 11-14, 22-24 and 27 were rejected under 35 U.S.C. § 112, first paragraph.

Independent claim 11 has been amended to recite a process for the preparation of amorphous atorvastatin calcium which comprises: a) provision of a reaction mixture having a pH between 6.5 and 8.0 containing a sodium salt of atorvastatin and tetrahydrofuran; b) addition of cyclic hydrocarbon solvent selected from the group consisting of cyclohexane and methyl cyclohexane to provide a mixture of organic solvents; c) addition of an equivalent or an excess quantity of a source of calcium ions selected from the group consisting of calcium acetate and calcium chloride and d) isolation of amorphous atorvastatin calcium from an organic phase comprising the mixture of organic solvents.

The process for the preparation of amorphous atorvastatin calcium recited in amended independent claim 11 now comprises four narrow steps:

In step a), a reaction mixture containing a sodium salt of atorvastatin and tetrahydrofuran is provided at a pH between 6.5 and 8.0. In step b), a cyclic hydrocarbon solvent selected from the group consisting of cyclohexane and methyl cyclohexane is added. A mixture of organic solvents is thereby obtained. To this mixture of organic solvents is added, in step c), an equivalent or an excess quantity of a source of calcium ions selected from the group consisting of calcium acetate and calcium chloride. In step d), amorphous atorvastatin calcium is isolated from an organic phase comprising the mixture of organic solvents.

Applicants respectfully submit that the claims of the present application as amended reasonably provide enablement for making amorphous atorvastatin calcium via the full scope of the

process presently claimed and that a person skilled in the art is able to practice the invention commensurate in scope with the present claims.

Withdrawal of the rejection of claims 11-14, 22-24 and 27 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

CONCLUSION

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

It is believed that no fees are required for these submissions. However, should the U.S. Patent and Trademark Office determine that any additional fee is required or that any refund is owed for this application, the Commissioner is hereby authorized and requested to charge any deficiency and/or credit any refund owed to our Deposit Account No. 04-0100.

Dated: February 5, 2009

Respectfully submitted,

By Norman B. Thot
Norman B. Thot
Registration No.: 47,993
DARBY & DARBY P.C.
1500 K Street, NW
Suite 250
Washington, DC 20005-1714
(202) 347-7865
(202) 347-7866 (Fax)
Attorneys/Agents For Applicant



Application No. (if known): 10/552,562

Attorney Docket No.: 21388/0209170-US0

Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. in an envelope addressed to: **EM168007115US**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on February 5, 2009
Date

Lillian Garcia
Signature

Lillian Garcia
Typed or printed name of person signing Certificate

Registration Number, if applicable

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Response to office Action (8 pgs.)
Return post-card.